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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

HM11/0319

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1646	10

DATE MAILED: 03/19/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 01/05/98

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 9 to 15, 19 to 22, 44 to 50 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 9 to 15, 19 to 22, 44 to 50 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

1) Claims 9 to 15, 19 to 22 and 44 to 50 are pending in the instant application. Claims 16 to 18 have been canceled and claims 9, 11 to 15, 19 to 22 and 44 to 50 have been amended as requested by Applicant in Paper Number 9, filed 05 January of 1998.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) Claim 19 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant specification does not provide an adequate written description of a nucleic acid which encodes a human scavenger receptor protein such that an artisan could make and use that nucleic acid for those reasons of record in section 4 of Paper Number 7.

Applicant has failed to identified the error in this rejection. This rejection is based upon the premise that, whereas a specification may be enabled for a genus of chemical

compounds, it is not enabled for a specifically recited species of that genus unless it identifies that material property or combination of properties which distinguishes the claimed species from the other members of the genus to which that species belongs. In the case of an isolated nucleic acid encoding a protein "X", a generic claim which encompasses any isolated nucleic acid encoding protein "X" is enabled by nothing more than the disclosure of the amino acid sequence of protein "X" since the genetic code and nucleic acid synthesis were well known in the art at the time of the instant invention. However, a claim to "a cDNA encoding protein "X"" would require the disclosure of the nucleotide sequence of a specific cDNA before an artisan could produce the claimed cDNA **to the exclusion** of all of the other nucleic acids encompassed by the generic claim "an isolated nucleic acid encoding a protein "X"". Because the instant application does not provide a written description of those material properties which distinguish "a human scavenger receptor" from any other mammalian scavenger receptor, a practitioner of the art can not produce the claimed nucleic acid to the exclusion of a nucleic acid encoding any other mammalian scavenger receptor. Further, the text beginning in the last paragraph on page 14 of the instant specification shows that one

can not isolate a genomic DNA encoding a human scavenger receptor by employing only routine experimentation, as asserted by Applicant.

5) Claims 9 to 13, 15, 17 19 to 22 and 44 to 50 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the production of an isolated nucleic acid encoding a scavenger receptor protein lacking one of the amino acid sequences that are disclosed in SEQ ID NOs:4, 6 and 8 of the instant application for those reasons of record in section 6 of Paper Number 7.

Applicant's argues that these claims now recite structural limitations by requiring the scavenger receptor protein to be encoded by a nucleic acid molecule which hybridizes to a nucleic acid molecule having one of the nucleotide sequence disclosed in the instant specification. This argument is not persuasive. Any nucleic acid molecule will "hybridize" to any other nucleic acid molecule under the appropriate conditions, irrespective of the degree of sequence similarity between the molecules being hybridized. Because nucleic acid hybridization is conditional and the instant claims recite no conditions, this element does not materially limit the claims.

This rejection is also based upon the premise that the instant claims encompass nucleic acids encoding proteins whose

amino acid sequences have been substantially altered from their natural forms whereas the instant specification does not provide the guidance that is required to produce such nucleic acids in a predictable manner. Applicant has not responded to this aspect of the rejection, which is maintained for those extensive reasons of record presented on pages 5 to 8 of Paper Number 7.

6) Claim 49 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This claim is drawn to a method of treatment by the administration of a compound of undisclosed composition. Applicant has urged that the claimed method is enabled because the figures in the instant application show that "such assays are routine and would require absolutely no undue experimentation". Applicant has apparently overlooked the fact that claim 49 is drawn to a method of treatment, not a binding assay. The instant specification does not provide a single working example of a method of treatment and does not provide the guidance needed for the practice of such a method for those reasons of record in section 7 of Paper Number 7. The fact that one can identify a compound which binds to one of the proteins described in the instant invention does not enable an

artisan to then routinely administered that compound in an effective manner in a clinical environment. The vast majority of compounds with desirable properties as determine by *in vitro* assays like the binding assay of the instant invention have proven to be useless in an *in vivo* application and most of those that have proven to be useful have required a substantial inventive contribution before an effective method of administration was developed. There is no dispute that the instant specification provides a method which can be used to identify compounds which inhibit the binding of AcLDL to a protein of the instant invention but the specification lacks that inventive contribution needed to employ the compounds identified thereby in a method of treatment.

7) Claims 44 to 50 stand rejected under 35 U.S.C. § 112, first paragraph, because they are incomplete. Each of these claims is drawn to a method and yet none of them recite sufficient elements to provide the claimed method. Claim 44, for example, includes the step of "providing reagents for use in an assay for binding" which still lacks any defining elements.

8) Claims 9 to 15, 19 to 22 and 44 to 50 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8.1) Claims 9 to 15, 19 to 22 and 44 to 50 are vague and indefinite because they recite the term "scavenger receptor protein type BI" as a limiting element and the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a scavenger receptor protein type BI. The fact that the claims recite additional elements does not avoid this rejection. A claim to "an isolated nucleic acid which hybridizes to a nucleic acid comprising the nucleic acid sequence of SEQ ID NO:## under stringent hybridization conditions" is not vague and indefinite so long as stringent hybridization conditions are define in the specification. A claim which is drawn to "an isolated nucleic acid encoding a protein X and which hybridizes to a nucleic acid comprising the nucleic acid sequence of SEQ ID NO:## under stringent hybridization conditions" is vague and indefinite in the absence of a clear and concise definition of what is included and excluded by the term "protein X". The two elements "encoding a protein X" and "which hybridizes to a nucleic acid comprising the nucleic acid sequence of SEQ ID NO:## under stringent hybridization conditions" are two properties of a nucleic acid which are not mutually inclusive nor is one a subset of the

other. The fact that a nucleic acid has either one of these properties does not mean that it will automatically have the other. Therefore, the fact that a claim recites the limitation "which hybridizes to a nucleic acid comprising the nucleic acid sequence of SEQ ID NO:## under stringent hybridization conditions" can not be relied upon as providing a definition for the term "a protein X".

8.2) Claims 9 to 12, 15, 19 to 22, and 44 to 50 are vague and indefinite because the term "hybridizing" is a conditional limitation and no conditions are recited in these claims.

8.3) Claim 9 is incorrect because there is no antecedent basis for "scavenger receptor protein type BI". There is no single protein which is identified in either the art of record or the instant specification as "scavenger receptor protein BI". This claim should properly refer to "a scavenger receptor protein BI" since the instant specification indicates that a plurality of different proteins are encompassed by the term "scavenger receptor protein BI".

8.4) Claim 14 remains vague and indefinite in the recitation of the term "or a degenerate variant thereof". Either the claimed nucleic acid encodes the amino acid sequence of SEQ ID NO:4 or it doesn't.

8.5) Claim 21 is vague and indefinite because the physical relationship between the "molecule of claim 11" and the "expression vector" is critical to the claim but not recited therein. This claim should be directed to "an expression vector comprising the molecule of claim 11".

8.6) Claim 22 is incorrect vague and indefinite because the physical relationship between the "composition of claim 21" and the "host cell" is critical to the claim but not recited therein. This claim should be directed to " a host cell comprising the

8.7) Claim 46 is confusing because the term "naturally occurring or synthetic compounds" implies that there is a third alternative.

9) Claims 11, 12, 15, 17, 19 and 20 stand rejected under 35 U.S.C. § 102(a) as being clearly anticipated by the Calvo et al. publication (J. Biol. Chem. 268(25):18929-18935, 05 Sept. 1993) for those reasons of record in section 11 of Paper Number 7. Applicant's reliance on interference case law in traversal of a rejection under 35 U.S.C. § 102(a) is grossly inappropriate. The only proper response is to establish prior invention of the claimed subject matter or to identify that element which is present in the instant claims but lacking in the subject matter of the prior art. 35 U.S.C. § 102(a) precludes the allowance of claims which encompass subject matter which "was described in a

printed publication in this or a foreign country, before the invention thereof by the applicant for a patent". Figures 2 and 3 on pages 18931 and 18932 of the Calvo publication provided a complete written description of an isolated cDNA which meets, either explicitly or implicitly, all of the limitations of the instant claims. Applicant is strongly encouraged to review M.P.E.P. 2131 before providing any further response to this rejection.

Applicant has antedated the Calvo et al. publication in so far as it is applicable to an isolated nucleic acid encoding a hamster CLA-1 protein by showing the isolation of a cDNA encoding hamster CLA-1 (a.k.a. BI) prior to the publication of the Calvo et al. publication. Contrary to Applicant's assertion, however, the declaration by Monty Krieger and Susan L. Acton, which was filed on 05 January of 1998 under 37 C.F.R. § 1.131, does not demonstrate that Applicant was in possession of any information regarding a CLA-1 protein or CLA-1 gene from any animal other than hamster prior to the publication of Calvo et al. There is no evidence in this declaration that a nucleic acid probe encoding all or part of hamster CLA-1 was capable of hybridizing to mouse DNA using Northern blots or that a DNA encoding a murine cDNA had been isolated. In fact, there was no evidence presented in that declaration to support a position that the hamster CLA-1

described therein was functionally and structurally predictive of an analogous protein from any other organism.

In re Clarke, 148 USPQ 665 (CCPA 1966) confirmed the position that "in an appropriate case, applicant should not be prevented from obtaining patent for an invention where compound described in reference would have been obvious to one of ordinary skill in the art in view of what affiant proves was completed with respect to invention prior to date of reference". Essentially, the court has stated that an applicant can antedate a reference which describes one species in a claimed genus by providing a declaration showing the prior invention of a different species **if** the reference species of the claimed invention would have been obvious in view of the material contained in that declaration in conjunction with a contemporary knowledge of the art prior to the publication of the reference being antedated.

The declaration by Monty Krieger and Susan L. Acton has only shown the isolation of hamster CLA-1 prior to the publication of the Calvo et al. publication. It has been well settled that an isolated DNA encoding a protein from one organism would **not** be obvious in view of an analogous protein from a different organism in the absence of evidence that the protein from either organism

would be structurally and functionally predictive of a protein from the other (see *Regents of the University of California v. Eli Lilly and Company*, 43 USPQ2d 1398 (CAFC 1997)). The declaration by Monty Krieger and Susan L. Acton does not show any structural or functional analogy between the single hamster protein described therein and any other protein which was known in the art at that time.

The current rejection over Calvo et al. as well as the rejection that was made in view of this reference in Paper Number 7 are consistent with current case law. With regard to the original rejection in Paper Number 7 of hamster CLA-1 in view of human CLA-1, *Ex parte Movva*, 31 USPQ 2d 1027 (BdPatApp&Int 1993) found that a cDNA encoding a swine growth hormone was obvious in view of prior art descriptions of cDNAs encoding bovine, human and rat growth hormones and the proteins encoded thereby, since the evidence in the prior art had shown that these compounds from different mammals had been **proven** to be structurally and functionally predictive of one another. No such evidence is present in the declaration by Monty Krieger and Susan L. Acton. Conversely, *Fiddes v. Baird*, 30 USPQ2d 1481 (BdPatApp&Int 1993) determined that a human protein identified therein as basic fibroblast growth factor (bFGF) was not obvious over a bovine

bFGF in the absence of evidence that one was structurally and functionally predictive of the other.

10) Claims 9, 10, 13, 14, 18, 19, 21 and 22 are rejected under 35 U.S.C. § 103 as being unpatentable over the Calvo et al. publication (J. Biol. Chem. 268(25):18929-18935, 05 Sept. 1993) for those reasons of record in section 12 of Paper Number 7.

11) Applicant's arguments filed 05 January of 1998 have been fully considered but they are not persuasive.

12) Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached at (703) 308-2957.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800